Peer Review of the ACIP Statement entitled "Prevention of Rotavirus Gastroenteritis Among Infants and Children: Recommendations of the Advisory Committee on Immunization Practices (ACIP)"

Clinical and Epidemiological Features of Rotavirus Disease

This section of the statement is derived primarily from published observational studies of rotavirus disease in the United States. The studies used to compile this section are the most relevant and up-to-date studies of rotavirus epidemiology available. This section provides a clear and accurate overview of the burden of disease in the US as well as the particular groups at risk of infection and severe disease.

Rationale for Rotavirus Vaccine

This section of the statement presents four reasons to adopt rotavirus vaccine to prevent infection. Each reason is clearly presented with the supporting literature cited. The rationale presented is clear and persuasive.

Morphology, Antigen Composition and Immune Response

This section reviews the basic virology of rotaviruses including the structure and function of the major surface problems. In addition the major serotypes of rotavirus are explained. The section also includes a clear review of what is known about protective immunity and how it develops. The section is clearly written and is appropriately referenced with the most current literature. Rotavirus immunity is not

completely understood and further research is needed to better define correlates of immunity.

Bovine Rotavirus-Based Pentavalent Rotavirus Vaccine (Rotateq®)

This section describes the development of this vaccine, its composition and the clinical trial data supporting vaccine recommendations clearly and completely. The immunogenicity, safety and efficacy data are derived from a phase III placebo-controlled, randomized trial that enrolled over 70,000 infants. Because of the large study population, the confidence intervals surrounding the various outcomes are quite tight. As a result, the conclusions about the safety and efficacy of the vaccine are supported by strong clinical trial evidence. Intussusception was a particular outcome of interest in the large clinical trial and appeared not to be associated with receipt of the vaccine. This outcome will be the subject of further study as part of the phase IV post-marketing trials since the large clinical trial cannot exclude very rare adverse events.

The recommendations for use of the vaccine are a logical outgrowth of the clinical trial data. Important areas where knowledge is currently lacking is in use of the vaccine in older infants, in those with underlying immunodeficiency and in patients with chronic gastrointestinal illnesses.

Cost-Effectiveness Analysis

This section summarizes the results of a cost-effectiveness analysis done by the CDC. The statement does not reference a prior cost-effectiveness analysis by Tucker nor does it state where the estimates of rotavirus disease burden, vaccine coverage rates and health care costs were derived. Addition of background data as described would strengthen this section.

Overall

I found the statement to be well written, and appropriately referenced. Gaps in our current knowledge are pointed out especially when a recommendation is made that has little supporting data. The statement is organized and the recommendations are supported, where possible, with scientific evidence.